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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,929	10/25/2000	Lee A. Bulla JR.	48279-USPT	4758

7590 09/10/2002

KATE H. MURASHIGE
MORRISON & FOERSTER
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/10/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,929

Applicant(s)

BULLA ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other _____

DETAILED ACTION

The preliminary amendments filed April 29, 2002, and June 17, 2002, have been received and entered.

Applicant's election in Paper No. 8, filed April 29, 2002, without traverse, of the group III invention, directed to methods of inhibiting the growth of a bacterium, presently including claims 47-58, all of the pending claims, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 47-58 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-52, 55 and 56 are rejected under 35 U.S.C. 112,

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first paragraph, because the specification, while being enabling for the inhibition of the bacteria described in claims 53, 54, 57 and 58, does not reasonably provide enablement for inhibiting the growth and development of any and all organisms encompassed by the recitation "mucoid organism." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the full scope of the invention commensurate in scope with these claims.

Specifically, the recitation "mucoid organism" can be construed to encompass any organism which contains mucus membranes, any organism which grows in mucus membranes, and any organism which produces mucus, mucopolysaccharides, or any substance similar to mucus or mucopolysaccharides. Thus, the claims encompass inhibiting the growth and development of a huge number of organisms having widely different properties, ranging for example from mammals to bacteria. However, applicant's specification demonstrates inhibition of only one microorganism, that described in claims 53, 54, 57 and 58. Because applicant demonstrates inhibition of only a single microorganism, one skilled in the art clearly would not consider applicant's disclosure predictive or instructive of whether and how the claimed process should be practiced with respect to the entire large range of organisms encompassed by the present claim

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language. A holding of lack of enablement, with the noted exception, is therefore required.

In sum, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 5 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "mucoid organism" is indefinite because it is not clear what organisms are encompassed by the recitation and what organisms are not. Specifically, it is not clear

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whether the recitation "mucoid organism" is limited only to organisms which contain mucus membranes, organisms which grow in mucus membranes, or organisms which produce mucus, mucopolysaccharides, or any substance similar to mucus or mucopolysaccharides. Because it is not clear what organisms are to be included or excluded by the recitation, a holding of indefiniteness is clearly required.

The recitation "propionic acid or a derivative thereof" is indefinite because it is not clear how similar to propionic acid the derivative must be to be encompassed by the claim. For example, combustion of propionic acid will ultimately yield carbon dioxide. Thus, carbon dioxide could be considered a "derivative" of propionic acid. In sum, because the term "derivative" fails to clearly delineate between claim-encompassed subject matter and non-claim-encompassed subject matter, a holding of indefiniteness is clearly required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-52, 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Chowdhury et al (Med. Sci. Res. 24:801-802 (1996)).

Chowdhury discloses the use of ibuprofen , 2-(4-isobutylphenyl) propionic acid for the inhibition of a variety of bacteria which inhibit mucus membranes, and therefore can be considered to fall within the claim term "mucoid organism." See page 801, disclosing the inhibition of *Staphylococcus aureus*, *S. epidermidis*, and *Streptococcus pneumoniae*, all of which are known to inhabit mucoid areas of humans. Thus, Chowdhury's contacting of these organisms with ibuprofen discloses not only the inhibition of growth and development, but also the inhibition of biofilm formation, since contacting the organisms with the anti-growth ingredient will inherently inhibit biofilm production. A holding of anticipation is clearly required.

No claims are allowed. However, claims 53, 54, 57 and 58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action and to include


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all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Frats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCF
September 5, 2002